Bringing an Implementation Mindset to Planning a Care Delivery Pragmatic Trial: Pilot & Prototyping Experience from the NOHARM trial

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RESEARCH OBJECTIVE

- Opioid abuse and addiction has become a prevalent issue plaguing the country
- For some, prolonged opioid use begins after receiving prescription opioids post-operatively[1,2]
- However, informing patients pre-operatively about pharmacologic and non-pharmacologic options may help reduce post-operative opioid use[3]
- We sought to develop a robust intervention (NOHARM) combining extensive non-pharmacologic patient education and selection of non-pharmacologic techniques pre-operatively, which the care team could support peri-operatively with the assistance of clinical decision support built into the electronic health record.
- Our funding mechanism required demonstration of proof of concept prior to the full NOHARM trial which seeks enrollment of ~114,000 patients across 7 surgical specialities and 6 trial sites. This allowed us to refine and test acceptability of patient materials and explore issues pertaining to implementation and feasibility with care teams.

STUDY DESIGN

- To assist in the refinement of a portal-based Healing After Surgery Guide and the website that provides information about different non-pharmacologic options that can help patients plan for and mange post-operative pain, our team conducted 26 hours of observations observing inpatient and outpatient nurses and interactions between patients and clinicians. Interviews were also conducted with surgical patients to determine their receptivity to non-pharmacologic education.
- To help develop training materials for surgical care team members and finalize clinical decision support built into electronic health record, we spoke to stakeholders at each of the 6 trial sites and conducted observations of neurosurgical workflows at 4 sites.
- We then conducted a pilot with patients undergoing a neurosurgery spine procedure, selected according to surgeon and surgery date, at 3 different sites within one health system.
- Following completion of the pilot, debriefing interviews were held with front-line providers to identify needed refinement to training and electronic clinical decision support. Pilot patients were interviewed about their experience using the Healing After Surgery portal-based guide.

SAMPLE

Pre-pilot
- Observed n = 14 patients and n = 11 clinicians from the gastroenterology and neurosurgery departments
- Interviewed n = 5 pre-surgical gastroenterology and neurosurgery patients and n = 3 post-surgical Mayo Clinic connect patients

Pilot
- n = 24 neurosurgery spine patients across 3 sites
- n = 7 post-surgical neurosurgery spine patient interviews
- n = 12 debriefing interviews with providers

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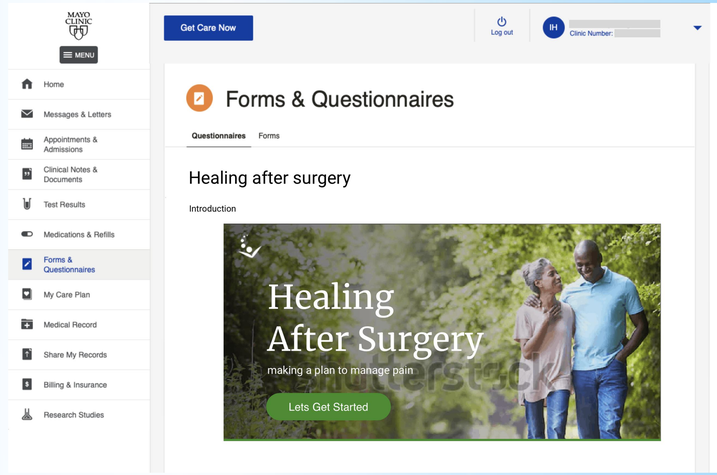
PRINCIPAL FINDINGS

Pre-pilot Findings

- Patients did not receive much pre-operative information on non-pharmacologic and pharmacologic options. However, patients demonstrated awareness of opioid risks discussed in the news and frequently mentioned it on their own.
- Patients welcomed the idea of receiving non-pharmacologic information post-operatively and liked presenting pain in this information as something that was a normal part of healing after surgery.
- After meeting with clinical stakeholders, we determined that online training modules were the best method for disseminating training due to the impracticality of conducting in person training with all nurses who could possibly care for a NOHARM patient.
- Additionally, we created laminated just-in-time (JIT) training sheets with screenshots depicting the clinical decision support elements added to EPIC to provide a refresher and assist cross-covering nurses who may not have viewed the online training.



Pilot Findings

- Nurses generally reported that the intervention was appropriate and compatible with their existing workflows and many of the non-pharmacologic modalities were already being provided

"This initiative, at least that I've noticed, requires little to no adjustment to the way that I already chart while also giving patients a wider array of pain relief measures." - RN

- However, identifying whether a patient was part of NOHARM was not obvious by looking at their chart, revealing the need to build an obvious banner at the top of patient's chart to identify patients.

"I think that with proper communication or a flag/banner on the NOHARM charts the nurses can be more proactive in working through patient's planned pain management strategies (I love that its more pro-active rather than re-active)"- RN

- The pilot revealed that online training was insufficient on it's own making the JIT key to helping nurses remember what to do.
- We identified ambulatory nursing supervisors as crucial individuals to engage because ambulatory nurses could both introduce the intervention to patients during pre-op visits and reinforce use of non-pharm options during post-op phone calls and visits. In the inpatient setting, clinical nurse specialists can serve as important champions to disseminate education and information
- We also confirmed compatibility of the intervention across different sites and identified adaptations (e.g. providing tablets at one trial site that did not have videos about the different non-pharm options available on their TVs).
- Lastly, patient interviews revealed that many patients had prior experiences with some of the non-pharmacologic techniques in the guide and were reminded to use and select options that they were familiar with.

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IMPLICATIONS FOR POLICY AND PRACTICE

- By conducting a proof of concept pilot as required by our funding mechanism, we were able to also asses acceptability and feasibility ensuring that the intervention works not just on technical level but at an individual and organizational level as well.
- Confirming acceptability of the patient facing electronic elements of the intervention both during the build and after we had a final product, increases our confidence that we have designed an intervention patients will engage with and buy into.
- We also detected some easy changes to the electronic health record that would have threatened study fidelity had they not been identified and addressed (e.g., the inability for providers to reliably detect which patients were in the study).

CONCLUSION

- By conducting clinical and patient observations and patient interviews to refine the portal based guide and intervention website, we increased the likelihood that patients would find the tool and its language acceptable because it was refined based on patient feedback. Pilot feedback revealed that this was indeed the case with patients generally having positive feedback about the guide.
- Our pilot also demonstrates the importance of testing training resources in a scenario where providers will have to practice what they learned. Our pilot revealed the need for JIT to be easily accessible to all nurses (not just cross-covering) and as a result we added a link to the JIT in the chart of all NOHARM patients.
- Piloting across three different sites also allowed us to proactively identify nuances between sites that may require tweaking of the intervention, increasing our confidence in the feasibility of conducting this intervention across multiple geographically diverse sites.